

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.**



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/111,911	07/08/1998	WILLIAM S. M. WOLD	16153-5587	6287

21888 7590 06/17/2002

THOMPSON COBURN, LLP  
ONE FIRSTAR PLAZA  
SUITE 3500  
ST LOUIS, MO 63101

EXAMINER

SHUKLA, RAM R

ART UNIT PAPER NUMBER

1632

DATE MAILED: 06/17/2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/111,911

Applicant(s)

WOLD, WILLIAM S. M.

Examiner

Ram Shukla

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1, 4, 7, 10, 13 and 23-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 4 and 23-25 is/are allowed.
- 6) ☒ Claim(s) 7, 10 and 13 is/are rejected.
- 7) ☒ Claim(s) 26 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *detailed action*.

**DETAILED ACTION**

1. The request filed on 4-2-02 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/111,911 is acceptable and a CPA has been established. An action on the CPA follows. It is noted that the applicants had filed an RCE under 37 CFR 1.114, however, the request was treated as a request for CPA as noted in the communication of 5-28-02, since the parent application was filed prior to 29 May 2000 and this was the first instance of continuation application filing.
2. Amendment/response filed 4-2-02 is acknowledged.
3. Claim 14 has been cancelled.
4. New claims 26 has been entered.
5. Amendments to claims 4, 7, 10 and 13 have been entered.
4. Claims 1, 4, 7, 10, 13 and 23-26 are pending.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 10, 13 remain rejected and the amended claim 7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an in vitro method of inhibiting apoptosis of a cell, wherein the cell expresses Fas, TNFR-1, DR-3, TRAIL-R1, or TRAIL-2, comprising, contacting the cell with an adenovirus comprising a CMV promoter operably linked to a polynucleotide that encodes a RIDa polypeptide, a RIDa-L, and a RIDp, disclosed in SEQ ID NO:1, SEQ ID NO: 2, and SEQ ID NO:4, wherein the adenovirus enters the cell, the RIDa polypeptide, a RIDcc-L, and a RIDp are expressed in the cell in an amount sufficient to inhibit apoptosis of the cell, the adenovirus lacks at least one functional E1 gene, the cell expresses Fas, DR3, TRAIL-R1, or TRAIL-R2, and the apoptosis is mediated

by Fas receptor activity, does not reasonably provide enablement for other embodiments for reasons of record set forth in the previous office action of 10-15-01 and 1-2-02.

It is noted that applicants have not presented any new arguments regarding the grounds of rejection set forth in the previous office action of 10-15-01 and 1-2-02. They have rather asserted that the claim 10 as amended does not rely on the fact that the murine model presented in example 9 is an art recognized model. Applicants further argue that example 9 describes transplantation of heterologous cells into an immunocompetent animal which were able to grow in the animal. While the claim 10 as amended recites a method of decreasing the rejection of transplanted cells compared to previously recited method of decreasing the rejection of cells in a patient, the amendment does not obviate the rejection set forth in the previous office actions of 1-2-02 since the method is interpreted as a method of treatment wherein cells are transplanted in a patient, the rejection of the cells is decreased, and the cells treat the disease such as degenerative disease or an immunodeficiency disease. As noted in the previous office action of 10-15-01, the specification is not enabling for the claimed invention because the mouse model disclosed in the specification is not an art recognized model of cell or tissue transplantation and rejection. Regarding claim 7, it is noted that as amended it depends from claim 4 which in turn depends from claim 1. While claim 1 is enabled, claim 7 is not enabled since its utility as recited in the claim is for transplantation in a patient, which is not enabled as discussed.

8. Claims 1, 4 and 23-25 are free of the prior art of record.

9. Claim 26 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See

MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

*If the claims are amended, added and/or canceled in response to this office action the applicants are required to follow Amendment Practice under 37 CFR § 1.121 (<http://www.uspto.gov>) and a clean copy of all pending claims is requested.*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for this Group is (703) 308-4242. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the Dianiece Jacobs whose telephone number is (703) 305-3388.

Ram R. Shukla, Ph.D.

  
RAM R. SHUKLA, PH.D.  
PATENT EXAMINER